(1/3)

MAR 2 5 2009

MEDSHAPE
SOLUTIONS

510(k) Summary

510(k) Number: K083792

Date Prepared: March 18th, 2008

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92.

A. Submitter:
MedShape Solutions, Inc.
1575 Northside Drive, Suite 440
Atlanta, Georgia 30318

B. Company Contact:
Jack Griffis
Vice President, Research & Development
(404) 249-9156 x11 (direct)
(404) 249-9158 (fax)
Jack.Griffis@MedShapeSolutions.com

C. Preparer:
Max Sherman
Sherman Consulting Services, Inc.
339 East Wildwood Drive
Warsaw, Indiana 46580
(574) 269-1928 (direct)
(574) 267-3845 (fax)

D. Device Information:
Trade Name: *WedgeLoc*™ Suture Anchor with *Opti-Fiber*™ Sutures
Common Name: Suture Anchor

E. Classification Name: Fastener, Fixation, Non-degradable, Soft Tissue
HWC/MBI and GAT 21 CFR 888.3040

F. Predicate Device(s):
Arthrex PushLock™ suture anchor, K051219
Arthrex FiberWIRE™ polyblend suture, K021434

G. Physical Description:

The proposed *WedgeLoc*™ Suture Anchor is a sterile, single use, two piece "push-in" bone anchor. The suture anchor is designed to use the principles of compression to force the eyelet, pre-loaded with non-absorbable suture, into a hole created in the bone. The suture anchor body is comprised of a crosslinked Methyl methacrylate (MMA) polymer (comprised of Memori™ 7111, refer to MAF #1533) and PEEK eyelet (comprised of PEEK-OPTIMA® by Invibio®, refer to MAF #1209).

Each suture anchor is preloaded with two non-absorbable USP No. 2 sutures. The polyblend surgical suture provided with the proposed *WedgeLoc*™ Suture Anchor is provided by CP Medical, and has previously been cleared for market under K041894. In addition, these sutures meet USP requirements as described in the USP monograph for non-absorbable surgical sutures. *Opti-Fiber*™ non-absorbable polyblend surgical sutures are made with a braided, twisted core of polyethylene terephthalate and a polyethylene cover and are identical to the CP-Fiber™ USP No. 2 sutures described in K041894. In addition, the predicate Arthrex FiberWIRE™ polyblend suture was listed as the predicate for the CP-Fiber™ in the premarket notification K041894.

H. Indications for Use:

The *WedgeLoc*™ Suture Anchor and *Opti-Fiber*™ sutures are indicated for fixation of suture to bone in the shoulder, foot/ankle, knee, hand/wrist and elbow in the following procedures:

Shoulder:	Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction
Foot/Ankle:	Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Mid-foot Reconstruction, Metatarsal Ligament Repair
Knee:	Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis
Hand/Wrist:	Scapholunate Ligament Reconstruction, Ulnar Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction
Elbow:	Biceps Tendon Reattachment, Tennis Elbow Repair, Ulnar or Radial collateral Ligament Reconstruction

1575 Northside Drive, Suite 440
Atlanta, GA 30318
404-249-9156 phone
404-249-9158 fax

K083792 (pg 3/3)

I. Comparison of Technological Characteristics:
The *WedgeLoc*™ Suture Anchor and *Opti-Fiber*™ sutures are substantially equivalent in design, function and intended use to the following predicate devices:

Arthrex PushLock™ suture anchor, K051219
Arthrex FiberWIRE™ polyblend suture, K021434

Both suture anchors are comprised of a two part assembly; main body and eyelet. The eyelets of both suture anchors are made from PEEK-OPTIMA® material. The main body of the proposed *WedgeLoc*™ Suture Anchor differs from the predicate device as it is comprised of a cross-linked Methyl methacrylate (MMA) (Memori™ 7111) instead of PEEK-OPTIMA® material. The Memori™ 7111 has successfully passed biocompatibility screening in compliance with ISO 10993:2003 Biological evaluation of medical devices (refer to MAF #1533). Both anchors are deployed using a "push in" or "tap in" process for securing their polyblend sutures into bone. Both suture anchors have the same indications for use.

Both predicate and proposed *Opti-Fiber*™ sutures are indicated for use in soft tissue approximation; both meet USP for non-absorbable sutures, may be silicone coated or uncoated, and may be dyed or undyed with an appropriate FDA listed color additive. The proposed *Opti-Fiber*™ suture has previously been cleared for market as per K041894.

Functional performance testing was conducted in-vitro. This testing was conducted in both cancellous and cortical bone analogues. Analysis of the results substantiates the statement that the proposed device performs as well as or better than the predicate device.

Jack Griffis
Vice President, Research & Development

MEDSHAPE
SOLUTIONS

1575 Northside Drive, Suite 440
Atlanta, GA 30318
404-249-9156 phone
404-249-9158 fax

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 25 2009

MedShape Solutions
% Mr. Jack Griffis
Vice President, Research & Development
1575 Northside Drive, Suite 440
Atlanta, Georgia 30318

Re: K083792
Trade/Device Name: WedgeLoc™ Suture Anchor with Opti-Fiber™ Sutures
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic fixation fastener
Regulatory Class: II
Product Code: HWC, MBI, GAT
Dated: March 18, 2009
Received: April 12, 2009

Dear Mr. Griffis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

For Peter D Rumm MD

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K083792 (pg 1/1)

Indications for Use

510(k) Number: K083792

Device Name: *WedgeLoc*™ Suture Anchor and *Opti-Fiber*™ Sutures

Indications for Use:

The MedShape Solutions, Inc., *WedgeLoc*™ Suture Anchor with *Opti-Fiber*™ Sutures are intended for fixation of suture to bone in the shoulder, foot/ankle, knee, hand/wrist, elbow and pelvis in the following procedures:

Shoulder:	Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction
Foot/Ankle:	Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Mid-foot Reconstruction, Metatarsal Ligament Repair
Knee:	Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis
Hand/Wrist:	Scapholunate Ligament Reconstruction, Ulnar Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction
Elbow:	Biceps Tendon Reattachment, Tennis Elbow Repair, Ulnar or Radial collateral Ligament Reconstruction

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K083792